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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/764,163

01/16/2001

Robert F. Balint

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06/20/2006

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EXAMINER

GROSS, CHRISTOPHER M

ART UNIT

PAPER NUMBER

1639

DATE MAILED: 06/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/764,163

Applicant(s)

BALINT ET AL.

Examiner

Christopher M. Gross

Art Unit

1639

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 29 March 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 70 and 84-88 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 70, 84-88 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 80 and 84-88 are pending. Claims 80 and 84-88 are under consideration.

Priority

This application is a CIP of application 09/526106 filed 3/15/2000 (now ABN) and also claims benefit to provisional application 60/175968 filed 1/13/2000.

Maintained Claim Rejection 35 USC § 112

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 80, 84-88 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Response to Arguments

Applicant argues (i) the meaning of the phrase "consisting essentially of" is well established in patent law and appears in at least 165 issued patents; (ii) the definiteness standard merely requires a reasonable degree of clarity; (iii) Claim 80 is clear and definite.

Applicants arguments, see p 5-11 3/29/2006 have been considered but they are not persuasive.

With regard the argument (p 5-9, 3/31/2006) "consisting essentially of" being well established and appearing in at least 165 patents, the Examiner concedes the meaning of "consisting essentially of" is well established in cases concerning variability of amino

acid sequences as well as applicants need for sufficient breadth to cover trivial changes (p 11 3/29/2006).

However, examination is done on a case-by-case basis and the novelty of the instant invention is less concerned with the exact amino acid sequence, but rather the stoichiometry and topology of polypeptides including the n terminal or "alpha" portion of circularly permuted beta-lactamase, the c terminal or "omega" portion of a circularly permuted beta-lactamase as well as multiple "interactor" domain(s) connected to the alpha and omega domains in numerous ways. The meaning of "consisting essentially of" is not certain in the instant case.

With regard to the argument that the definiteness standard merely be reasonable (p 8-9 3/29/2006): as currently written, the claim is ambiguous and therefore vague and indefinite as to what element of the claim the phrase "consists essentially of" is actually referring to.

Applicant's arguments (3/31/2006) suggest the variability construed by "consisting essentially of" refers to the primary amino acid sequence, yet in the manner in which the claim is constructed, one of skill in the art could just as reasonably conclude, that it is the topology or binding stoichiometry that varies. Because both the alpha and omega domains will **each** have [new] amino (N) and [new] carboxy (C) termini, *even if the protein is circularly permuted*, the claims can be read as comprising *two* tandem interactor domains connected to a portion of beta lactamase (e.g. alpha or omega) at both the amino and carboxy *simultaneously*. The claims can also read as

comprising a single interactor domain connected to the amino terminus of a portion of beta lactamase. Other meanings are similarly possible.

Therefore "consisting essentially of" permits the claim to have multiple meanings and introduces variability into the claim, yet one of skill in the art is not adequately apprised as to what element(s) of the claim is(are) variable.

Because the element of the claim to which "consisting essentially of" is referring is (are) thereby rendered vague and indefinite, the metes and bounds of the claim are unascertainable and hence the rejection is hereby maintained.

Withdrawn Provisional Claim Rejection: Double Patenting

The provisional rejection of claims 80, 84-88 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 63-65 of copending Application No. 09/526,106 is withdrawn in light of the express abandonment of application 09/526,106.

Maintained Provisional Claim Rejection: Double Patenting

Claims 80, 84-88 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 63-74 of copending Application No. 10/668,778.

Applicant does not provide arguments concerning non-obvious differences between the instant application and copending application 10/668,778, therefore the instant rejection is maintained. The claims remain provisionally rejected.

Conclusion

Claims 80 and 84-88 stand finally rejected.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

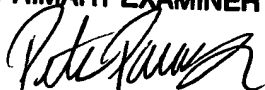
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher M. Gross whose telephone number is (571)272-4446. The examiner can normally be reached on M-F 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on 571 272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

PETER PARAS, JR.
PRIMARY EXAMINER



Christopher M Gross
Examiner
Art Unit 1639

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